IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, v. PATRICK MORRISEY, in his official capacity as ATTORNEY GENERAL OF THE STATE OF WEST VIRGINIA, ALLAN L. MCVEY, in his official capacity as INSURANCE COMMISSIONER OF WEST VIRGINIA, and JOHN BERNABEI, in his official capacity as BOARD PRESIDENT OF THE WEST VIRGINIA BOARD OF PHARMACY, and JAMES RUCKER, JENNA MISITI, SAM KAPOURALES, DAVID G. BOWYER, DENNIS LEWIS, and ROBERT DUNCAN, in their official capacities as MEMBERS OF THE WEST VIRGINIA BOARD OF PHARMACY, *Defendants*.	Civil Action No. 2:24-cv-00272

VERIFIED COMPLAINT

Plaintiff Novartis Pharmaceuticals Corporation brings this Complaint against Defendants Patrick Morrisey, in his official capacity as the Attorney General of the State of West Virginia, Allan L. McVey, in his official capacity as the Insurance Commissioner of West Virginia, John Bernabei, in his official capacity as the President of the West Virginia Board of Pharmacy, and James Rucker, Jenna Misiti, Sam Kapourales, David G. Bowyer, Dennis Lewis, and Robert

Duncan, in their official capacities as Members of the West Virginia Board of Pharmacy, and alleges as follows:

PRELIMINARY STATEMENT

1. This is an action for temporary, preliminary, and/or permanent injunctive relief challenging the constitutionality of West Virginia's S.B. 325, which purports to dramatically expand the scope of a federal law mandating the sale of covered outpatient drugs at a discounted price to "covered entities"—non-profit hospitals and clinics meeting specified statutory criteria.

2. The Supreme Court has held that state laws cannot be used to enforce the federal 340B statute, which requires drug manufacturers to provide deeply discounted prices on their covered outpatient drugs to qualifying covered entities. *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110 (2011). That decision makes sense: The federal 340B Program is a unified federal regulatory scheme, carefully constructed by Congress, and governed by a comprehensive framework of federal statutes and regulations that collectively define the obligations imposed on regulated entities. Allowing states to tinker with the federal framework would undermine Congressional objectives.

3. S.B. 325 directly conflicts with Congress's carefully designed federal program and is therefore preempted by federal 340B law. The West Virginia law requires manufacturers to provide the federal 340B discount on an unlimited number of transactions involving for-profit pharmacies (known as "contract pharmacies"). Several federal courts (including the Third Circuit, the D.C. Circuit, and the District Court for the District of Columbia) have held that federal 340B law does *not* require manufacturers to recognize an unlimited number of contract pharmacies. Yet that is precisely what West Virginia's S.B. 325 purports to mandate, greatly expanding the scope of the federal discounting obligation in conflict with federal law.

4. S.B. 325 further conflicts with the federal 340B enforcement process by purporting to create its own state-level 340B enforcement mechanism. Congress created two exclusive pathways to resolve disputes arising under the 340B statute: (i) direct enforcement by federal agencies, and (ii) an Administrative Dispute Resolution process that serves as the exclusive means for regulated entities to bring narrow types of private claims relating to 340B law. Congress gave no authority to the States to administer, interpret, or enforce any aspect of the 340B Program. Yet S.B. 325 purports to do exactly that.

5. The West Virginia law also is preempted by federal laws governing the timing of drug approvals, including federal patent laws and the Food, Drug, and Cosmetic Act (FDCA) as amended by the federal Drug Price Competition and Patent Term Restoration Act (commonly known as the Hatch-Waxman Act). In these statutes, Congress spelled out a grand bargain: Brand name manufacturers are driven to research, develop, and bring to market pharmaceutical products on the promise that they will obtain federally protected, exclusive rights to sell their products at market prices for specified periods of time. Once those periods expire, generic manufacturers are permitted to rely upon the drug development work done by innovator manufacturers by obtaining streamlined approval of generic products. S.B. 325 requires Novartis to make its drugs that are not covered by the federal 340B framework available at heavily discounted prices *before* those federally protected exclusivity periods have run, undermining the bargain carefully constructed by federal law. That frustrates the purposes of Congress.

6. Absent immediate judicial intervention enjoining S.B. 325, Novartis will suffer irreparable harm. Once the law becomes effective on June 6, 2024, Novartis will risk violating West Virginia law merely by continuing to implement a contract pharmacy policy that has already been expressly declared lawful by other federal courts applying the federal 340B law. If S.B. 325

is not enjoined, Novartis will continue to suffer severe irreparable harm and loss of its constitutional rights on an ongoing basis. Novartis therefore requests a preliminary injunction enjoining enforcement of S.B. 325 pending a decision on the merits.

7. For all of these reasons, Novartis brings this action seeking a declaration that S.B. 325 is unconstitutional and a temporary, preliminary, and/or permanent injunction barring Defendants from enforcing S.B. 325 against Novartis.

PARTIES

8. Plaintiff Novartis is a corporation organized in Delaware with its principal place of business at 59 Route 10, East Hanover, New Jersey 07936. Novartis's purpose is to reimagine medicine to improve and extend people's lives.

9. Defendant Patrick Morrisey is the Attorney General for the State of West Virginia and is responsible for administering and enforcing the provisions of S.B. 325. Defendant Morrisey maintains an office at 1900 Kanawha Blvd. E, Charleston, WV 25305.

10. Defendant Allan L. McVey is the Insurance Commissioner of West Virginia and is also responsible for administering and enforcing the provisions of S.B. 325. Defendant McVey maintains an office at 900 Pennsylvania Avenue, Charleston, WV 25302.

11. Defendant John Bernabei is the President of the West Virginia Board of Pharmacy and is also responsible for administering and enforcing the provisions of S.B. 325. Defendant Bernabei maintains an office at 1207 Quarrier Street, 4th Floor, Charleston, WV 25301.

12. Defendant James Rucker is a Member of the West Virginia Board of Pharmacy and is also responsible for administering and enforcing the provisions of S.B. 325. Defendant Rucker maintains an office at 1207 Quarrier Street, 4th Floor, Charleston, WV 25301.

13. Defendant Jenna Misiti is a Member of the West Virginia Board of Pharmacy and is also responsible for administering and enforcing the provisions of S.B. 325. Defendant Misiti maintains an office at 1207 Quarrier Street, 4th Floor, Charleston, WV 25301.

14. Defendant Sam Kapourales is a Member of the West Virginia Board of Pharmacy and is also responsible for administering and enforcing the provisions of S.B. 325. Defendant Kapourales maintains an office at 1207 Quarrier Street, 4th Floor, Charleston, WV 25301.

15. Defendant David G. Bowyer is a Member of the West Virginia Board of Pharmacy and is also responsible for administering and enforcing the provisions of S.B. 325. Defendant Bowyer maintains an office at 1207 Quarrier Street, 4th Floor, Charleston, WV 25301.

16. Defendant Dennis Lewis is a Member of the West Virginia Board of Pharmacy and is also responsible for administering and enforcing the provisions of S.B. 325. Defendant Lewis maintains an office at 1207 Quarrier Street, 4th Floor, Charleston, WV 25301.

17. Defendant Robert Duncan is a Member of the West Virginia Board of Pharmacy and is also responsible for administering and enforcing the provisions of S.B. 325. Defendant Duncan maintains an office at 1207 Quarrier Street, 4th Floor, Charleston, WV 25301.

JURISDICTION AND VENUE

18. Jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331, in that this civil action arises under the laws of the United States, and under 28 U.S.C. §§ 2201–02, in that there exists an actual justiciable controversy between the parties as to which Plaintiff requires a declaration of its rights by this Court and injunctive relief.

19. This Court also has inherent equitable powers to enjoin the actions of state officials that contradict the U.S. Constitution and federal law. *Ex parte Young*, 209 U.S. 123, 159–160 (1908); *United States v. South Carolina*, 720 F.3d 518, 526 (4th Cir. 2013).

20. Venue is proper in this Court under 28 U.S.C. §§ 1391(b)(1) and (2) because one or more defendants reside in this district and/or because a substantial part of the events or omissions giving rise to the claim occurred in this district. The challenged state law also applies to contract pharmacy arrangements in this district.

21. Novartis brings an "action seeking injunctive relief" where irreparable harm would result "if the institution of the action were delayed by the provisions" of the notice period described under West Virginia law. W. Va. Code § 55-17-3(a)(1). This action is thus exempted from the requirement that a party asserting a claim against the State give 30 days' notice before filing suit, and the statutory notice provisions "do not apply" to Novartis's Complaint and request for preliminary injunctive relief. *Id.*

FACTUAL BACKGROUND

I. Statutory and Regulatory Background

22. Congress created the 340B Drug Pricing Program in 1992. The program requires participating pharmaceutical manufacturers to provide deep discounts on certain drugs to specified types of healthcare providers—known as "covered entities"—as a condition of the availability of federal payments for such drugs under Medicaid and Medicare Part B. 42 U.S.C. § 256b.

23. At its core, the 340B Program requires a participating pharmaceutical manufacturer to charge a covered entity no more than the 340B ceiling price—a discounted price calculated under a prescribed statutory formula—for each unit of a covered outpatient drug. *Id.* §§ 256b(a)(1), (a)(4), (b)(1). A participating manufacturer "shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* § 256b(a)(1).

24. The 340B Program is overseen by the federal Department of Health and Human Services (HHS) and its sub-agency, the Health Resources and Services Administration (HRSA). To participate in the 340B Program, a manufacturer must enter a Pharmaceutical Pricing Agreement (PPA) with the federal government. 42 U.S.C. § 256b(a)(1).

25. The "applicable ceiling price," or "340B price," is a steeply discounted rate—as low as one penny—calculated under a prescribed statutory formula. *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1214-15 (Jan. 5, 2017); 42 U.S.C. § 256b(a)(2).

26. Congress intentionally limited the scope of sales that would trigger such a severe discount to those drugs "purchased by a covered entity." 42 U.S.C. § 256b(a)(1). The statute carefully defined the term "covered entity" in a specific and exhaustive way, listing 15 types of entities that qualify for the discount. *Id.* § 256b(a)(4) (listing federal grantees, black lung clinics, family planning projects, and specified types of non-profit hospitals). The statute does not require that the 340B discount be given to entities not included within the definition of "covered entity."

27. In the first several years of the program, covered entities dispensed 340B-purchased drugs exclusively through their own in-house pharmacies. But over time, covered entities sought to be able to dispense 340B-purchased drugs through contractual arrangements with third-party pharmacies (so-called "contract pharmacies") as well. Under these arrangements, instead of drugs being shipped to the covered entity for dispensing by its in-house pharmacy, drugs are shipped to the contract pharmacy—often a large, national chain—for dispensing there.

28. Contract pharmacy arrangements, including those in West Virginia, traditionally involve a "virtual inventory" or "replenishment" model. Under this model, the contract pharmacy starts with an inventory of commercially purchased product and dispenses all units of the drug

from this common inventory, regardless of whether the individual to whom a unit is dispensed is a patient of the covered entity. That is because the contract pharmacy itself typically has not determined at the time of dispensing whether the individual receiving the prescription is a "patient" of the covered entity. That determination is made afterward. Where it believed, based on an opaque formula generally not shared with the manufacturer, that the individual is a covered-entity patient, the covered entity purchases a "replenishment" unit at the 340B price and directs shipment to the contract pharmacy—which commingles the 340B-purchased unit with commercially purchased units in its common inventory. The 340B replenishment unit is treated as it if had been purchased at the commercial price—and thus is available for dispensing to anyone, including a non-patient of the covered entity—even though it has in fact been purchased at the 340B price. *See Novartis Pharms. Corp. v. Johnson*, No. 21-5299 (D.C. Cir. May 21, 2024) ("Slip Op."), at 16–18; *see also* HHS OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 at 5 (Feb. 4, 2014), *available at* https://oig.hhs.gov/oei/reports/oei05-13-00431.pdf.

29. The statute provides for only two enforcement mechanisms. First, the statute provides for the imposition of civil monetary penalties (CMPs) on manufacturers that knowingly and intentionally charge a covered entity a price for a 340B drug that exceeds the ceiling price. 42 U.S.C. § 256b(d)(1)(B)(vi)(III). HRSA has taken the position that implementation of this statutory remedy requires a referral to the HHS Office of Inspector General (OIG).

30. In addition, the statute required the Secretary of HHS to promulgate regulations establishing an ADR process to resolve specific categories of private disputes between covered entities and manufacturers arising under the 340B Program. 42 U.S.C. § 256b(d)(3). The statute specifically describes two narrow claim categories that are funneled to administrative dispute

resolution: (1) "claims by covered entities that they have been overcharged for drugs purchased under this section," and (2) claims by manufacturers relating to duplicate discounts and drug diversion. 42 U.S.C. § 256b(d)(3)(A). In promulgating ADR regulations, the agency has recently interpreted these provisions—rightly or wrongly—to include a claim "that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 89 Fed. Reg. 28,643, at 28,657 (Apr. 19, 2024).

31. There are no other enforcement mechanisms contemplated by the 340B statute.

II. HRSA's Changing Position on Contract Pharmacies

32. Over time, HRSA's position on contract pharmacies has evolved.

33. In 1996, the agency issued guidance announcing that the agency would not preclude covered entities lacking an in-house pharmacy from entering into a contractual relationship with a single outside pharmacy to dispense covered outpatient drugs to the covered entity's patients. 61 Fed. Reg. 43,549 (Aug. 23, 1996).

34. In 2010, HRSA issued revised guidance on contract pharmacy arrangements, stating that covered entities may be permitted to "use" an untold number of "multiple pharmacy arrangements"—with no limits on their physical location, and even if the covered entity had its own in-house pharmacy—"as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). HRSA's 2010 Guidance thus purported to authorize covered entities to enter into a limitless number of contract pharmacy arrangements with any pharmacy located anywhere in the United States.

35. That decision had striking consequences. Over the ensuing years, the number of contract pharmacies receiving and distributing 340B drugs grew at a rapid clip. By 2018, the

Government Accountability Office found that the number of contract pharmacies had ballooned from 1,300 in 2010 to nearly 20,000 by 2017. Government Accountability Off., *Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 36 (June 2018), https://www.gao.gov/assets/gao-18-480.pdf. This report echoed findings from the Department of Health and Human Services' Office of Inspector General, which similarly documented dramatically increased use—and abuse—of 340B discounts through covered entities' contract pharmacy relationships. HHS OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, No. OEI-05-00431 at 9–10, 16 (2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

36. Neither covered entities nor their contract pharmacies are required to pass on 340B discounts to patients, and often they do not. Instead, covered entities and contract pharmacies are permitted to (and often do) pocket the discount themselves. Over time, 340B expenditures have swelled as contract pharmacy arrangements, and the profits they generate for covered entities and contract pharmacies alike, proliferated. By 2020, sales of 340B units constituted an estimated 7% of the entire U.S. prescription drug market and 17% of all total U.S. branded outpatient drug sales. Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments* (Oct. 14, 2021), *available at* https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments; Eleanor Blalock, *Measuring the Relative Size of the 340B Program*, *available at* https://media.thinkbrg.com/wp-content/uploads/2022/06/30124832/BRG-340B-Measuring-Relative-Size-2022.pdf. In 2022, discounted purchases under the 340B Program hit a record high of approximately $54 billion—a more than 22% year-over-year increase. *Id.*; *see also* Adam J. Fein, *The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023).

III. Novartis's Contract Pharmacy Policy and Resulting Litigation

37. Concerned about ever-increasing abuse through fast-multiplying contract-pharmacy arrangements, in late 2020, Novartis notified HRSA of its plans to implement a contract pharmacy policy. Beginning in November 2020, Novartis explained, it would recognize all contract pharmacies within 40 miles of a covered entity—an area of more than 5,000 square miles—and allow covered entities to seek exemptions based on individual circumstances. Novartis's 40-mile limitation did not apply to covered entities that are federal grantees.

38. In early 2021, HRSA issued a violation letter to Novartis, contending that Novartis's policy violated the statute and demanding immediate compliance with HRSA's view that, at the unilateral direction of a covered entity, a manufacturer is obligated to deliver 340B drugs to any contract pharmacy, on pain of an enforcement action.

39. Upon receiving HRSA's violation letter, Novartis immediately challenged the agency action in the U.S. District Court for the District of Columbia. *See Novartis Pharms. Corp. v. Espinosa*, No. 1:21-cv-01479 (D.D.C.) (filed May 31, 2021). Novartis's challenge was heard alongside a later case brought by United Therapeutics, which had also received a violation letter. *See United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686 (D.D.C.).

40. Following full briefing and argument, the District Court vacated HRSA's violation letters and issued a decision rejecting HRSA's purported requirement that manufacturers recognize an unlimited number of contract pharmacies as inconsistent with the language of the 340B statute. *Novartis Pharms. Corp. v. Espinosa*, No. 21-CV-1479, 2021 WL 5161783 (D.D.C. Nov. 5, 2021). As the District Court explained, HRSA's enforcement letters rested on the contention that the 340B statute "prohibit[s] drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies," but that the 340B statute does no such thing. *Id.* at *9. In sum, the

District Court held that "[t]he statute's plain language, purpose, and structure do not prohibit drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies." *Id.*

41. On May 21, 2024, the D.C. Circuit affirmed, holding that the federal 340B statute's "requirement to 'offer' drugs at a certain 'price' does not prohibit distribution conditions, much less require the offeror to accede to any distribution conditions, much less require the offeror to accede to any distribution terms demanded by the offeree." *Novartis Pharms. Corp. v. Johnson*, Slip Op., at 16. The D.C. Circuit also noted that statutory silence on contract pharmacies does not mean that manufacturers are required to recognize an unlimited number of them. "Statutory silence implies that manufacturers may impose distribution conditions by contract, not that they are prohibited from doing so." *Id.* at 14. The Court thus held that Novartis's contract pharmacy policy does not violate the federal 340B statute, and affirmed the vacatur of HRSA's violation letter.

42. In a parallel lawsuit brought by other drug manufacturers, the U.S. Court of Appeals for the Third Circuit likewise rejected the notion that Section 340B requires manufacturers to recognize an unlimited number of contract pharmacy arrangements. *See Sanofi Aventis U.S. LLC v. United States Dep't of Health & Human Servs.*, 58 F.4th 696 (3d Cir. 2023). The unanimous Third Circuit panel held unlawful HHS's efforts to enforce its interpretation of Section 340B against drug manufacturers that imposed delivery conditions on sales to covered entities using contract pharmacies. *Id.* at 699. In so doing, the Third Circuit held that "Section 340B does not require delivery to an unlimited number of contract pharmacies." *Id.* at 703. It identified multiple structural indicators that confirmed this reading of Section 340B.

43. Critically, the Third Circuit noted that "[n]owhere does Section 340B mention contract pharmacies," and inferred based on the language and structure of the statute that Congress's decision to omit contract pharmacies from the list was not an unintentional gap, but was done intentionally. The Court noted, Congress "expressly contemplate[d] drug makers selling discounted drugs through contract pharmacies" in an adjacent provision of the same authorizing legislation relating to another (non-340B) program, but did not include similar language for the 340B program. *Id.* at 703–705.

44. The Third Circuit also rejected the argument that manufacturers are required to deliver their 340B drugs anywhere that covered entities wish, including to third party contract pharmacies, as "one giant leap from the text." *Id.* at 704. To the contrary, "Congress's use of the singular 'covered entity' in the 'purchased by' language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies." *Id.* Because the "drug makers' restrictions on delivery to contract pharmacies [did] not violate Section 340B," the Third Circuit "enjoin[ed] HHS from enforcing against them its reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies." *Id.* at 706.

45. Following both the D.C. District Court's and the Third Circuit's decisions, Novartis announced in April 2023 that it was revising its contract pharmacy policy, effective May 3, 2023. In keeping with both decisions, Novartis's current policy permits hospital covered entities lacking an in-house pharmacy to select a single contract pharmacy location. Novartis also recognizes any arrangements a hospital covered entity might have with contract pharmacies that the covered entity fully owns and controls. Federal grantee covered entities continue to be exempt. *See* Ex. A (April 3, 2023 Letter to Covered Entities on 340B Contract Pharmacy Policy). Novartis's revised policy

mirrors one of the manufacturer policies that the Third Circuit found lawful, and has now also specifically been found lawful by the D.C. Circuit.

IV. West Virginia Enacts Its Own "340B" Legislation.

46. On March 8, 2024, West Virginia passed S.B. 325, which states in relevant part that a manufacturer "shall not, either directly or indirectly, deny, restrict, or prohibit the acquisition of a 340B drug by, or delivery of a 340B drug to, a location authorized by a 340B entity to receive such 340B drug." S.B. 325 (to be codified at W. Va. Code § 60A-8-6a(b)(1)).[1]

47. A "340B drug" is defined as "a covered outpatient drug within the meaning of" the federal 340B statute that has "been subject to any offer for reduced prices by a manufacturer" under the federal 340B statute and "purchased by a covered entity within the meaning of" the federal 340B statute." S.B. 325 (to be codified at W. Va. Code §§ 60A-8-6a(a)(1)(A)-(C)). In other words, a "340B drug" is a drug that is sold at a 340B discount.

48. A "340B entity" is defined to mean "an entity participating in the federal 340B drug discount program," including its pharmacy or pharmacies, or any pharmacy "contracted with the participating entity to dispense drugs purchased through such program." *See* S.B. 325 (to be codified at W. Va. Code § 60A-8-6a(a)(2) (referencing *id.* § 33-51-3)).

49. Putting these definitions together, the West Virginia statute requires manufacturers like Novartis to provide the 340B discount on transactions that involve contract pharmacies.

50. A manufacturer in violation of S.B. 325 faces penalties on numerous fronts. The statute provides for a fine of "$50,000 per each violation." S.B. 325 (to be codified at W. Va.

[1] *Available at* https://www.wvlegislature.gov/Bill_Text_HTML/2024_SESSIONS/RS/bills/sb325%20sub2%20enr.pdf.

Code § 60A-8-6a(c)(1)(A)). Each "package of 340B drugs determined to be subject to a prohibited act" constitutes a separate violation. *Id*. (to be codified at W. Va. Code § 60A-8-6a(c)(2)).

51. A "package" carries the same meaning as that term is defined in 21 U.S.C. § 360eee(11)(A), which is "the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product." S.B. 325 (to be codified at §60A-8-6a(a)(7)).

52. A violation of S.B. 325 also subjects a manufacturer to "any and all actions, including investigative demands, remedies, and penalties provided for" in the West Virginia Consumer Protection and Credit Act. S.B. 325 (to be codified in W. Va. Code § 60A-8-6a(c)(1)(A)).

53. In addition, a violation of S.B. 325 subjects a manufacturer to "any and all actions, including . . . civil penalties, and restitution provided for" in West Virginia's Unfair Trade Practices Act, except for private causes of action. S.B. 325 (to be codified at W. Va. Code § 60A-8-6a(c)(1)(B)). If an entity is found to have engaged in an unfair trade practice under the Unfair Trade Practices statute, the Insurance Commissioner shall issue a cease and desist order and may impose monetary penalties of up to $100,000 in a six month period. W. Va. Code § 33-11-6(a). Penalties may range from not more than $1,000 for each violation up to an aggregate of $10,000, unless the entity knew or reasonably should have known it was in violation of the statute, in which case the penalties may range from not more than $5,000 per violation up to an aggregate of $100,000 in a six month period. *Id.*

54. In short, the penalties for a violation of S.B. 325 are dire.

S.B. 325 VIOLATES THE SUPREMACY CLAUSE

55. S.B. 325 is preempted by federal law, under both field and conflict preemption principles.

56. Field preemption exists where (1) Congress's "framework of regulation [is] 'so pervasive' " that Congress has "left no room for the States to supplement it," or (2) where there is a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). State statutes that diminish federal control over enforcement, and detract from a unified regulatory scheme that Congress has established, are especially likely to violate the Supremacy Clause under field preemption principles.

57. The 340B Program is just that sort of integrated federal regulatory scheme. It is a creature of a federal statute in which Congress has set out comprehensive regulatory parameters, closed off the regulatory system from state interference, and supplied an exclusively federal framework for enforcement and dispute resolution. The federal 340B statute mentions states only in passing and even then only in a limited way: The definition of covered entity includes hospitals that are "owned or operated by a unit of State or local government"; "State-operated AIDS drug purchasing assistance program[s] receiving" certain federal "financial assistance"; and "entit[ies] receiving [federal] funds" to treat sexually transmitted diseases or tuberculosis "through a State or unit of local government" are all federally defined covered entities. 42 U.S.C. §§ 256b(a)(4)(E), (K), (L)(i).

58. In crafting the 340B statute, Congress created a comprehensive federal regime—one that carefully defined the types of entities that are entitled to receive the 340B discount, and

provides its own enforcement pathways for violations of the statute, including civil penalty assessments, administrative appeal pathways, and audits initiated by the agency and/or manufacturers. *See* 42 U.S.C. §§ 256b(a) and (d)(3)(A)–(B). For that reason, the Supreme Court has held that the federal 340B program is to be administered—and enforced—*solely* by or through the federal government. State law claims seeking to separately enforce the 340B statute are preempted. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011).

59. By purporting to create a separate, state-specific pathway that adjusts the contours of the federal 340B requirements—altering when the discount is owed, and overriding federal restrictions on who can enforce it—S.B. 325 runs afoul of the Supreme Court's admonition that using state law to enforce federal 340B requirements is "incompatible with the statutory regime." *Astra*, 563 U.S. at 113. Congress has left "no room for the States to supplement it[s]" federal regulatory scheme. *Arizona*, 567 U.S. at 399.

60. Field preemption also exists when a federal interest is so dominant that it must be assumed the federal system precludes enforcement of state laws covering the same subject. The federal interests in overseeing and enforcing the 340B Program could hardly be more dominant. Congress directed HHS to create an exclusive and comprehensive remedial scheme, which allows for federal enforcement as well as private ADR claims "to prevent overcharges and other violations of the discounted pricing requirements" and to govern disputes over 340B discount pricing. 42 U.S.C. §§ 256b(d)(1)(A), (d)(2)(A), (3); 42 C.F.R. §§ 10.3, 10.20. Just as private lawsuits by state actors seeking to apply state common law to enforce 340B requirements are "incompatible with the [340B] statutory regime," so too is a state statute purporting to do the same thing. *Astra*, 563 U.S. at 113.

61. S.B. 325 also is preempted by the federal 340B statute under conflict preemption principles. State laws are preempted under conflict principles where they stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Conflict preemption is also found when a state law "interferes with the methods by which the federal statute was designed to" achieve those purposes and objectives. *International Paper Co. v. Ouellette*, 479 U.S. 481, 492, 494 (1987).

62. In particular, S.B. 325 conflicts with federal law by purporting to unilaterally expand the universe of 340B-eligible sales well beyond those required by the statute itself. As the D.C. Circuit, the Third Circuit, the District Court for the District of Columbia, and the District Court for the District of Delaware recognized, the federal 340B statutory scheme does not require that a drug manufacturer honor unlimited contract pharmacy arrangements. *See Sanofi Aventis*, 58 F.4th at 703; *see also Novartis Pharms. Corp.*, 2021 WL 5161783, at *6. By Congressional design, whether to recognize covered entities' contract-pharmacy arrangements is purely a matter of manufacturer discretion. Yet S.B. 325 purports to require manufacturers to make their 340B drugs available in connection with an unlimited number of contract pharmacy arrangements, in conflict with federal law as interpreted by multiple courts.

63. In addition, S.B. 325 conflicts with the exclusive enforcement mechanism spelled out in the 340B statute. Congress made its intent plain: The federal 340B program must be enforced by a specialized federal administrative agency, and only that agency, through one of two centralized administrative processes: one driven by federal actors pursuing CMPs and other penalties, and the other driven by private claimants who file specified ADR claims before HRSA.

64. In *Astra USA*, county-operated 340B facilities filed a lawsuit against various drug manufacturers, alleging that they were charging prices in excess of those permitted under the

manufacturers' PPAs. 563 U.S. 110. The plaintiffs' claims were styled as third-party beneficiary claims for breach of contract under state law. The Court rejected the plaintiffs' attempt to manufacture a state law right of action for violations of the 340B statute, noting: "Congress placed the Secretary (acting through her designate, HRSA) in control of § 340B's drug-price prescriptions. That control could not be maintained were potentially thousands of covered entities permitted to bring suits alleging errors in manufacturers' price calculations." *Id*. at 114.

65. As with the state common law remedy that the Supreme Court overturned in *Astra*, S.B. 325 erects a substantial obstacle to that centralized federal process by creating a separate enforcement pathway for covered entities outside of the federal enforcement process. West Virginia's law flouts the oversight scheme mandated by Congress and allows covered entities to bypass federal enforcement pathways. For all these reasons, S.B. 325 is unenforceable under the Supremacy Clause. *See Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 326 (2016).

66. Finally, S.B. 325 is preempted by federal laws governing patent protection and regulatory exclusivity periods for drug products. Congress has plenary authority under the U.S. Constitution to establish and oversee the patent laws, which provide a system of incentives "[t]o promote the Progress of Science and useful Arts." Art. I, § 8, cl. 8. In 1984, Congress enacted the "Hatch-Waxman" amendments to the FDCA, which among other things created a framework for patent litigation between brand manufacturers and generic manufacturers. Under the resulting framework, innovative manufacturers are "impelled to invest in creative effort" on the promise that they will obtain "a federally protected 'exclusive right'" to sell their inventions for a limited period. *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1371–74 (Fed. Cir. 2007) ("*BIO*").

67. These patent exclusivity periods are distinctively federal and leave no room for state interference. "Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc*., 489 U.S. 141, 152 (1989); *Southeastern Pennsylvania Transp. Auth. v. Gilead Scis., Inc*., 102 F. Supp. 3d 688, 703 (E.D. Pa. 2015) ("Federal patent law contemplates the tradeoffs between exclusivity and access, and plaintiffs cannot use state law to adjust that balance by forcing Gilead to lower its prices or disgorge profits from the sale of its patented drugs.").

68. State laws that cap or fix the prices at which patented drugs may be sold are preempted by federal patent law because they attempt to re-balance the carefully constructed federal statutory scheme that allocates rewards and incentives to innovator manufacturers. *See, e.g.*, *Pharmaceutical Rsch. & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 60 (D.D.C. 2005), *aff'd sub nom. Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1371–74 (Fed. Cir. 2007) ("*BIO*").

69. In *BIO*, the Federal Circuit held that a D.C. law that capped the price of patented pharmaceutical products was preempted by the federal patent laws. *See Biotechnology Indus. Org.*, 496 F.3d 1362. "Inventors are impelled to invest in creative effort by the expectation that, through procurement of a patent, they will obtain a federally protected 'exclusive right' to exclude others from making, using, or selling embodiments of their invention." *Id.* at 1372. The Court noted that the legislative history of the Hatch-Waxman Act supports this goal: "Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities." *Id.* at 1373 (citing legislative history). The Court thus found that the "underlying determination about the

proper balance between innovators' profit and consumer access to medication, though, is exclusively one for Congress to make"—and a state may not "re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* at 1374. "By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* The Court thus found the D.C. law preempted.

70. The same delicate balance underlies the federal exclusivity periods awarded to drugs as part of the drug approval process. Congress has spelled out a grand bargain: Manufacturers are driven to research, develop, and bring to market pharmaceutical products through a rigorous New Drug Application pathway, which requires manufacturers to submit clinical trials showing safety and efficacy. Brand name manufacturers do so on the promise that they will obtain a federally protected, exclusive right to sell their products for a specified period of time after approval, known as a "regulatory exclusivity period."

71. Congress thus directed the Food and Drug Administration (FDA) to recognize various periods of market exclusivity following approval of new drugs in order to reward manufacturers for innovation undertaken at considerable risk and expense. *See* 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii) (five years exclusivity for new chemical entities not previously approved by the FDA); *id.* § 355(c)(3)(E)(iii)-(iv), (j)(5)(F)(iii)-(iv) (three years exclusivity to reward additional clinical testing for new indications or to develop new dosages); *id.* § 355a (six months additional exclusivity for pediatric clinical testing); *id.* § 360cc (seven years exclusivity for "orphan drugs" used to treat rare diseases).

72. Once those exclusivity periods expire, generic manufacturers are permitted to utilize the drug development work done by innovator manufacturers in order to obtain streamlined

approval of generic products—without the need to show safety or efficacy through clinical trials. The public reaps the benefit of immediate access to a new product during the innovator manufacturer's exclusivity period, and cheaper products once those periods expire.

73. By requiring Novartis and other manufacturers of brand-name drugs to offer the steep 340B discount on sales made through contract pharmacy arrangements, even during the marketing exclusivity periods they are due under federal law, S.B. 325 impermissibly diminishes the reward that federal law confers on manufacturers, which in turn redounds to the benefit of patients who gain access to Novartis's life-saving and life-sustaining drug products.

V. S.B. 325 Will Cause Concrete and Imminent Harm to Novartis.

74. Novartis will be irreparably harmed unless this Court enjoins Defendants from enforcing S.B. 325.

75. First, if S.B. 325 is not enjoined, Novartis will be exposed to unconstitutional state-law obligations, and will risk violating West Virginia law by continuing with a policy that fully complies with federal law (as determined by multiple federal courts). A regulated entity may be irreparably injured in the face of the threatened enforcement of a preempted law. *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992).

76. Failure to comply with the state law will also subject Novartis to state administrative enforcement proceedings that are themselves unlawful and unconstitutional. These state pathways deprive Novartis of its rights under the carefully crafted, federally defined terms of the 340B Program enforcement pathways. These deprivations of constitutional rights constitute irreparable injury for purposes of a preliminary injunction.

77. Novartis also faces the prospect of significant financial penalties for violations of S.B. 325. As noted above, the state statute contemplates a fine of $50,000 "per each violation,"

which is defined to mean "each package of 340B drugs determined to be subject to a prohibited action under subsection 9(b) of this section." S.B. 325. Novartis thus risks exposure to fines totaling millions of dollars per year. In addition, Novartis faces penalties under the Consumer Protection and Credit Act and financial penalties and restitution under the Unfair Trade Practices Act. This money will divert resources away from Novartis's research and development of new drug therapies for critical patient populations. Once lost, drug development research opportunities and market-leading opportunities can never be fully regained.

78. If Novartis tries to avoid these stringent fines and financial penalties by coming into compliance with the state statute, Novartis faces the loss of millions of dollars in unconstitutional state-mandated discounts per year. Novartis has no readily apparent way to recover these unlawfully mandated discounts once given. In fact, HRSA's position is that a manufacturer may only seek recovery through the federal ADR process only on claims relating to duplicate discounts and drug diversion. 42 U.S.C. § 256b(d)(3)(A).

79. Granting injunctive relief here would not harm Defendants, as it is well-established that states maintain no interest in enforcing a statute that violates federal law.

80. Injunctive relief also would serve the public interest. The public has a substantial interest in seeing that federal law is enforced and not countenancing state efforts to reset the metes and bounds of participation in federal healthcare programs.

CLAIM FOR RELIEF

COUNT I
(Declaratory/Injunctive Relief—
Preemption Under the Supremacy Clause, U.S. Const. art. VI, cl. 2)

81. Novartis realleges, reasserts, and incorporates by reference herein each of the foregoing allegations as though set forth fully herein.

82. The Supremacy Clause of the U.S. Constitution provides that Federal law is "the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

83. S.B. 325 is preempted by the federal 340B statute under both field preemption and conflict preemption principles.

84. First, S.B. 325 is preempted because it attempts to regulate in a field that Congress has fully occupied. In crafting the 340B statute, Congress created a comprehensive and self-contained federal regime—one that carefully defines the types of entities that are entitled to receive the 340B discount, and provides its own enforcement pathways for violations of the statute, including civil penalty assessments, administrative appeal pathways, and audits initiated by the agency and/or manufacturers. *See* 42 U.S.C. §§ 256b(a) and (d)(3)(A)–(B). Congress left no room for states to tinker with the parameters of the federal law. Nor is there space for states to add their own enforcement mechanisms to the two exclusive enforcement pathways spelled out in the federal statute.

85. Field preemption also exists when a federal interest is so dominant that it must be assumed the federal system precludes enforcement of state laws covering the same subject. The federal interests in overseeing and enforcing the 340B Program could hardly be more dominant. Congress directed HHS to create an exclusive and comprehensive remedial scheme, which allows for federal enforcement as well as private ADR claims "to prevent overcharges and other violations of the discounted pricing requirements" and to govern disputes over 340B discount pricing. 42 U.S.C. §§ 256b(d)(1)(A), (d)(2)(A), (3); 42 C.F.R. §§ 10.3, 10.20. State statutes that seek to adjust and enforce the federal 340B law are "incompatible with the [340B] statutory regime." *Astra,* 563 U.S. at 113.

86. S.B. 325 also is preempted because it imposes a substantial obstacle to the achievement of federal purposes and objectives under the 340B statute. The West Virginia law requires manufacturers to provide the federal 340B discount on an unlimited number of transactions involving contract pharmacies. Several federal courts (including the Third Circuit, the D.C. Circuit, and the District Court for the District of Columbia) have held that federal 340B law does *not* require manufacturers to recognize an unlimited number of contract pharmacies. Yet that is precisely what West Virginia's S.B. 325 purports to mandate, greatly expanding the scope of the federal discounting obligation in conflict with federal law.

87. S.B. 325 also conflicts with the federal 340B enforcement process by purporting to create its own state-level 340B enforcement mechanism. Congress created two exclusive pathways to resolve disputes arising under the 340B statute: (i) direct enforcement by federal agencies, and (ii) an Administrative Dispute Resolution process that serves as the exclusive means for regulated entities to bring narrow types of private claims relating to 340B law. Congress gave no authority to the States to administer, interpret, or enforce any aspect of the 340B Program. Yet S.B. 325 purports to do exactly that.

88. And by purporting to reduce the value of the exclusivity periods and patent terms that the FDCA and federal patent laws guarantee to qualifying drug manufacturers, S.B. 325 is preempted under conflict preemption principles because it interferes with the careful balance of rewards and incentives that Congress crafted—a framework in which States simply play no role.

PRAYER FOR RELIEF

For the foregoing reasons, Novartis prays for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that S.B. 325 is preempted by federal law and is thus null, void, and unenforceable;

B. Temporary, preliminary, and permanent injunctive relief vacating S.B. 325 and enjoining Defendants from implementing and/or enforcing S.B. 325 against Novartis or any of its affiliates, officers, agents, representatives, or contractors;

C. Temporary, preliminary, and permanent injunctive relief enjoining Defendants from seeking civil penalties, equitable relief, or any other remedy based on an alleged violation under S.B. 325 by Novartis or any of its affiliates, officers, agents, representatives, or contractors;

D. An order awarding Novartis attorneys' fees, costs, and expenses, as appropriate; and

E. Such other and further relief as the Court deems just and proper.

Respectfully submitted,

Dated: May 31, 2024

/s/ Carte P. Goodwin

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**Pro Hac Vice Motion Forthcoming*

Attorneys for Novartis Pharmaceuticals Corporation

VERIFICATION

I, the undersigned, having read the allegations of the foregoing Verified Complaint, hereby declare under penalty of perjury and pursuant to 28 U.S.C. § 1746 that the factual allegations asserted in the Verified Complaint are true and correct.

Executed this 31st day of May, 2024.

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